

**REMARKS**

In the Final Office Action mailed July 17, 2007, claims 20-60 were pending and stand rejected. Reconsideration of the present application including claims 20-60 in view of the remarks that follow is respectfully requested.

Claims 20-36, 39-41, 43-48 and 50-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,505,732 to Michelson in view of U.S. Patent No. 6,258,125 to Paul et al. “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (In re Kahn, 441, F. 3d 977, 988 (CA Fed. 2006) cited with approval in KSR Int’ v. Teleflex Inc., 127 S. Ct. 1727 (2006)). In the present case, the Examiner fails to articulate any reasoning with any rational underpinning as to why one skilled in the art would modify Michelson according to the teachings in Paul et al. to arrive at the invention recited in claims 20-36, 39-41, 43-48 and 50-52. Applicant’s have not repeated the arguments made in the previous response for the sake of brevity, but incorporate them herein by reference and will focus herein supplementing those arguments and responding to the Examiner’s reasoning for maintaining the rejections.

In the “Response to Arguments” the Examiner disagrees with Applicant’s argument that the prior art does not disclose “first and second transition surfaces each having a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane.” The Examiner provides a definition of “correspond” and then concludes that the “curvature of the prior art references naturally all contain at least one curve and are all therefore similar in structure to anything else that has a curvature. The inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane has a curvature, therefore the curvature of the prior art references is similar in structure to the curvature of the inner portion of a cortical rim located at a posterior region of the vertebral endplates in a sagittal plane, and the curvatures correspond.” The Examiner further concludes that “the geometric points found along the curvature of the devices and geometric points along the curvature of the inner portion of a cortical rim could be related

“e.g. graphically/mathematically) and the curvatures would therefore correspond in that manner also.”

A review of Paul et al. indicates that it discloses and teaches that “[r]ounded edges 30 enable implant 10 to slide between the endplates while minimizing the necessary distraction of the end plates.” Col. 4, lines 18-20. This rounded profile facilitates insertion between the end plates at the outer portion of the cortical rim. Paul et al. also teaches that the rounded edges 30 “enable spacer 120 to slide between the end plate and across the evacuated disc space (from one lateral annulus to the other) to the contralateral side.” See col. 6, lines 31-34. There is no other disclosure or teaching relating to the curvature of the transition surfaces of the implants in Paul et al. Accordingly, the teachings of Paul et al. suggest an implant with transition surfaces that are curved to facilitate insertion at the outer edges of the cortical rim and then to facilitate movement of the implant once it is positioned between the vertebrae.

In contrast to the curvature of the implants in Paul et al., Applicant’s specifically claim a distractor with curvatures so that “said first and second transition surfaces each having a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane.” The Examiner fails to identify any disclosure in Paul et al. that would teach or suggest to one skilled in the art to modify the distractor in Michelson in the claimed manner, but rather concludes that because the implant in Paul et al. includes curved surfaces those surfaces correspond to the transition surfaces recited in claim 20. It is respectfully submitted that one skilled in the art, when presented with the teachings of Paul et al. to provide curvatures to the implant that promote movement of the implant in the disc space, would be led away from modifying the distractor of Michelson in the manner asserted by the Examiner. To facilitate the Examiner’s understanding of the significance of the claimed invention, Applicant’s specification discloses that the distractor tip with the configuration recited in claim 20 “is self-locating in the spinal disc space to the location where its geometrical configuration most closely matches that of the vertebral endplates, and any tendency for distractor tip 900 to move after it is positioned in the disc space is thus reduced.” See Applicant’s specification, page 33, lines 23-26. Furthermore, the disclosed and claimed curvatures allow the distractor tip to be “located in the disc space in contact with the

inner cortical rim, and any tendency for distractor tip 900 to move laterally or distally in the disc space is resisted by contact between the cortical rim and body 904.” See Applicant’s specification, page 37, line 29 to page 38, line 3. Since Paul et al. teach curvatures that facilitate movement of the implant in the disc space, these curvatures cannot be properly considered to teach or suggest the claimed curvatures that resist movement of the distractor in the disc space. Accordingly, it is not proper for the Examiner to assume that any curvature of the implant in Paul et al. corresponds to the claimed curvature, and as such a prima facie case for rejecting claim 20 has not been established. Withdrawal of this basis of the rejection of claim 20 is respectfully requested.

Each of claims 21-36 depends from claim 20 or an intervening claim and are submitted as patentable for at least the reasons supporting the patentability of claim 20 and for other reasons. For example, claim 36 recites “a third transition surface extending between said distal end surface and said lateral surface, said third transition surface having a second curvature generally corresponding to a curvature of the inner portion of the cortical rim of vertebral endplates in an axial plane.” The Examiner refers to Figure 9 of Paul et al. and asserts that the surface between the lateral surface and distal end surface includes these features. However, there is no disclosure in Paul et al. that this surface is curved. Rather, the surface appears linear and angularly oriented relative to the lateral and distal end surface of the implant in Figure 9. Accordingly, withdrawal of the rejection of claims 21-36 depending from claim 20 is respectfully requested.

Independent claim 39 also recites, among other features, “. . . wherein at least one of said first and second distractor tips includes a first transition surface extending between a distal end surface of said at least one distractor tip and said first surface of said at least one distractor tip and a second transition surface extending between said distal end surface and said second surface of said at least one distractor tip, said first and second transition surfaces each having a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane...” Claim 39 is submitted as patentable over the cited references for at least the reasons set forth above in support of the patentability of claim 20. For example, neither of the references teaches or suggests a transition surface having a curvature shaped to generally correspond in shape to a curvature of an inner

portion of a cortical rim located at a posterior region of vertebral endplates. Additionally or alternatively, as discussed above, Paul et al. provide no suggestion or motivation to modify Michelson as suggested by the Examiner. Accordingly, withdrawal of the rejection of claim 39 and allowance of same are respectfully requested. Each of claims 40, 41, and 43-45 depends directly from claim 39 and is submitted as patentable for at least the reasons supporting the patentability of claim 39.

Independent claim 46 recites, among other features, "... wherein at least one of said first and second distractor tips includes a lateral surface opposite the other of said first and second distractor tips when positioned therealong and a first transition surface extending between a distal end surface of said at least one distractor tip and said lateral surface, said first transition surface having a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim of vertebral endplates in an axial plane...." The Examiner asserts that one having skill in the art would be motivated to modify the distractor in Michelson in view of the implants 70, 70' disclosed in Figure 9 of Paul et al. to arrive at the invention of claim 46. However, for reasons similar to those submitted above with respect to claims 20 and 36, claim 46 is also submitted as patentable over the combination of references. For example, Paul et al. do not disclose or suggest that any portion of the implants 70, 70' in Figure 9 has "a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim" in an axial plane. Rather, the implant in Figure 9 includes a linear, angular surface between the distal end surface and the lateral surface of the implant. Moreover, even if implants 70, 70' included the same rounded surface 30 of spacer 120 in Figure 15, rounded surface 30 is disclosed to include a configuration that facilitates movement of the implant in the disc space as discussed above with respect to claim 20. See col. 5, lines 8-13. The Examiner fails to identify any disclosure in Paul et al. that would teach or suggest to one skilled in the art to modify the distractor in Michelson in the claimed manner, but rather concludes that because the implant in Paul et al. includes curved surfaces those surfaces correspond to the transition surfaces recited in claim 46. It is respectfully submitted that one skilled in the art, when presented with the teachings of Paul et al. to provide curvatures to the implant that promote movement of the implant in the disc space, would be led away from modifying the distractor of Michelson to

arrive at the claimed invention. Since Paul et al. teach curvatures that facilitate movement of the implant in the disc space, these curvatures cannot be properly considered to teach or suggest the claimed curvatures that resist movement of the distractor in the disc space. Accordingly, it is not proper for the Examiner to assume that any curvature of the implant in Paul et al. corresponds to the claimed curvature, and as such a prima facie case for rejecting claim 46 has not been established. Withdrawal of this basis of the rejection of claim 46 is respectfully requested.

Each of claims 47-48 and 50-52 depends directly from base claim 46 and is submitted as patentable for at least the reasons provided for claim 46 and for other reasons. For example, claim 48 recites, among other features, "said second and third transition surfaces each having a second curvature generally corresponding to a curvature of the inner portion of the cortical rim located at a posterior region of vertebral endplates in a sagittal plane." As indicated above with respect to claim 20, the combination of Michelson and Paul et al. does not teach or suggest this feature as well. Withdrawal of this basis of the rejection of claims 47-48 and 50-52 depending from claim 46 is respectfully requested.

Claims 53, 54 and 58-60 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Michelson in view of U.S. Patent No. 5,766,252 to Henry et al. Independent claim 53 is directed to a surgical assembly for distracting a spinal disc space and recites, among other features, "... wherein at least one of said first and second distractor tips includes a lateral surface opposite the other of said first and second distractor tips when positioned therealong and a first transition surface extending between said lateral surface and said first surface and a second transition surface extending between said lateral surface and said second surface, said first and second transition surfaces each having a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim of vertebral endplates in a coronal plane. . ." The Examiner asserts that the Michelson patent discloses all of the features of claim 53 except for the first and second transition surfaces which are instead taught by Henry et al. Henry et al. discloses implants configured for use during a posterior lumbar interbody fusion (PLIF) procedure that include, as shown in Figures 4 and 5, sides 28 which have a convex arcuate surface contour. However, contrary to the language of claim 53, the Henry patent does not disclose that the sides 28 each include first and second transition surfaces between surfaces 24

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and 26. Rather, each side 28 includes a single surface between surfaces 24 and 26. Furthermore, where each side 28 connects to surface 24, 26, there is provided a sharp, angular corner rather than a curved transition surface. Still further, there is no teaching or suggestion that this angular corner includes any curvature, let alone "a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim of vertebral endplates in a coronal plane" as recites in claim 53. Consequently, the combination of Michelson and Henry et al. fails to teach or suggest all the claim limitations in claim 53 and withdrawal of the rejection of the same is respectfully requested.

Each of claims 54 and 58-60 depends from claim 53 or an intervening claim and is submitted as patentable for at least the reasons supporting the patentability of claim 53. Therefore, withdrawal of this basis of the rejection of claims 54 and 58-60 depending from claim 53 is respectfully requested.

Dependent claims 37, 38, 42 and 49 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Michelson in view of Paul et al. in further view of Henry et al. These claims are allowable at least since each depends directly or indirectly from an allowable base claim. Furthermore, as discussed above with respect to claim 53, Henry et al. fails to provide the necessary teaching or suggestion missing from Paul et al. to modify Michelson to include transition surfaces that "generally correspond in shape to a curvature of the inner portion of the cortical rim of vertebral endplates in a coronal plane" as recited in claim 37, 42 and 49 or to provide each distractor with "transition surfaces each having a second curvature shaped to generally correspond in shape to a curvature of the inner portion of the cortical rim of vertebral endplates in a coronal plane" as recited in claim 38. Withdrawal of the rejection of claims 37, 38, 42 and 49 is respectfully requested.

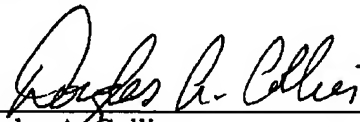
Dependent claims 55-57 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Michelson in view of Henry et al. in further view of Paul et al. These claims depend from claim 53 and are allowable at least for the reasons claim 53 is allowable. Furthermore, as discussed above with respect to claims 20 and 36, Paul et al. fails to provide the necessary teaching or suggestion missing from Henry et al. to modify Michelson to provide "transition surfaces each having a second curvature generally corresponding to a curvature of the inner

portion of the cortical rim located at a posterior region of vertebral endplates in a sagittal plane” as recited in claim 55 or a “transition surface having a curvature generally corresponding to a curvature of the inner portion of the cortical rim of vertebral endplates in an axial plane” as recited in claim 56. Withdrawal of this basis of the rejection of claims 55-57 is respectfully requested.

### CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance with pending claims 20-60. Reconsideration of the subject application and withdrawal of the final rejection of the claims is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

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